DEC 27 2004

510(k) SUMMARY
K040975

1.0 Submitted By:

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2.0 Date of Preparation: June 1, 2004

3.0 Regulatory Information:

3.1 Regulation section:
3.2 21 CFR § 862.1160, pH Rate Measurement, Carbon Dioxide

3.3 Clasification : Class II

3.4 Product Code: JFL

3.5 Panel: Clinical Chemistry (75)

4.0 Device Description:

The Device is a solution containing 0.6 mol/L sulfuric acid, nonreactive surfactants and other ingredients necessary for optimum system operation.

5.0 Substantial Equivalence Information:

a. Predicate Device Name: Beckman CO2 Reagent for the CX3.
b. Predicate K Number: K014034
c. Comparison with Predicate: Both Reagents are similar in design, function and chemical principle as well as ingredient composition and concentration.

6.0 Performance Characteristics: All studies were performed on the Beckman CX3 Synchron Analyzer

6.1 Precision/Reproducibility:

Three control sera were each assayed for total CO2 twice per day in triplicate using flow cell reagents, wash solutions and calibrators on a SYNCHRON CX3® System. Data were collected on ten different days over a thirty day period.

Estimates of within run and total imprecision were calculated as described in NCCLS publication EP3-T.10

Precision of Total CO2 Recoveries (mmol/L)

	Within Run			Total Imprecision		
Sample	n	mean	SD	%CV	SD	%CV
Serum 1	60	12.6	0.40	3.2	0.38	3.0
Serum 2	60	22.2	0.32	1.4	0.36	1.6
Serum 3	60	30.9	0.53	1.7	0.66	2.1

6.2 Linearity/assay reportable range:

Linearity was performed according to NCCLS Guideline EP6-A. Commercially available linearity standards ranging from 0 to 40 mmol/L were analyzed in triplicate on the Beckman CX3® and the results analyzed by the Least Squares method. The results gave a slope of 1.000 with an intercept of 0.15, a standard error of estimate of 0.41 and r^2 = 1.000. Samples exceeding these limits should be diluted with normal saline and reanalyzed. Multiply the result by the appropriate dilution factor.

	Usable Ranges	
Instrument	Conventional Units	SI Units
CX3®	0.0 to 40.0 mmol/L	same

6.3 SENSITIVITY:

The sensitivity of this method is 5.0 mmol/L and was documented through the repetitive assay of a diluted serum control. The observed sensitivity limit, calculated as three standard deviations of a 21 replicate within run precision study, is 0.255 mg/dL and is below the claimed limit of 5.0 mg/dL.

6.4 Analytical Specificity:

Determined according to NCCLS EP7-A. Hemoglobin levels up to 500 mg/dL, Bilirubin levels up to 20 mg/dL, and Lipemia levels up to 1800 mg/dL were tested and did not show any adverse effect on a stock sample with a glucose level of 19 mmol/L. Stock solutions of the substance to be tested were prepared at 20x

concentrations and 0.5 ml of this stock was placed in a 10 ml volumetric flask and made up to volume with the base pool. The control stock was prepared similarly but with water as the diluent. Sodium Heparin, Lithium Heparin, Ammonium Heparin, sodium fluoride and potassium oxalate are acceptable anticoagulants.

Patient Comparison

Serum and plasma specimens, collected from adult patients, were assayed for total CO2 on a SYNCHRON CX3® System using GenChem (Y) and Beckman®(X) flow cell reagents, wash solutions and calibrators. Results were compared by least squares linear regression and the following statistics were obtained.

VALUE	SERUM	PLASMA
Intercept	1.2	1.0
Slope	0.949	0.979
R^2 Value	0.953	0.987
N	80	80
Range (mmol/L)	9.5 – 29.1	9.6 – 30.0

7.0 Expected Values/ Reference Range:

The expected values for total CO2 are listed below. Use these ranges only as guides. Each laboratory should establish its own normal ranges.

Normal Ranges

Specimens	Conventional Units	SI Units
Serum/Plasma	22 - 29 mmol/L	same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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C.C. Allain, Ph.D.
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Re: k040975
Trade/Device Name: GenChem CO2 Acid Reagent
Regulation Number: 21 CFR 862.1160
Regulation Name: Bicarbonate/carbon dioxide test system
Regulatory Class: Class II
Product Code: JFL
Dated: October 15, 2004
Received: October 15, 2004

Dear Dr. Allain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Cornelia B. Rooks

Cornelia B. Rooks, MA
Acting Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number: K040975

Device Name: GenChem CO2 Acid Reagent

Indications For Use:

The GenChem CO_2 Acid Reagent when used in conjunction with the GenChem ISE Electrolyte Reference, GenChem Electrolyte Buffer, GenChem CO2 Alkaline Buffer, GenChem Wash Concentrate, and appropriate Calibrators or Calibration Standards is intended for the quantitative determination of Carbon Dioxide in serum and plasma on the Beckman CX3®. Carbon Dioxide results are used in the diagnosis and treatment of numerous and potentially serious disorders associated with changes in the body's acid-base balance.

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K040975

Prescription Use__X__ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)